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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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10/554,238

12/11/2006

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PUG201

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12/19/2008

EXAMINER

GRASER, JENNIFER E

ART UNIT

PAPER NUMBER

1645

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|---------------------------------------|--|--|
| Office Action Summary | Application No. 10/554,238 | Applicant(s) BREITENSTEIN ET AL. | |
| | Examiner Jennifer E. Graser | Art Unit 1645 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 is/are pending in the application.
4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-3 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 October 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/20/05</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Specification

The disclosure is objected to because of the following informalities:

The titles of the invention on pages 1 and 2 of the instant specification do not match one another, nor do they match the current title of the Application.

The specification should be amended to include the sequence identification numbers following the sequences recited on page 2, in both the text and the Table.

The application listed as US Patent No. 5,569,568 on page 1, last paragraph, does not recite sandwich hybridization assays. It appears this may be a typographical error.

In claims 2 and 3 the phrase "patent claim" in line 1 of each claim should be changed to solely "claim".

Appropriate correction is required.

Claim Rejections - 35 USC § 112-2nd paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite as it contains several periods. Accordingly, it is unclear that the hybridization temperatures recited in the second paragraph are part of claim 1 and the periods after parts (a)-(d) should be changed to semi-colons. The claim

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is also vague and confusing because it is unclear whether or not all four steps are performed on the same sample in the same method or if these represent separate assays. The claim must also be amended to include the sequence identification numbers of each of the 8 sequences recited in the claim. It is also suggested that the word "consisting" be inserted after the phrase "an oligonucleotide probe..." in parts a)-d) of the claim, e.g., an oligonucleotide probe consisting of the sequence" to convey that the probes cannot be any longer than the recited sequence. Clarification and correction is requested.

Claim 1 is also vague and confusing because the preamble recites a method for detection of the genus *Legionella*, yet parts (b)-(d) are directed to detection of species.

Claim 1 is also rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: there is no contact step, wash step, detection step, correlation step, etc..

Claim 2 is vague and confusing because it appears that the species detection would only be successful if the capture and detection probes for that particular species were exchangeable and not any of the species capture and detection probes as encompassed by the language of the current claim. Correction is requested.

Claim 3 is vague and indefinite because it is unclear what is meant by 'combinations of oligonucleotide probes for a genus and a species specific detection'. It appears that for a species specific detection the probes would have to be specific for

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that particular species and one could not use *any* of the *L.pneumophila* probes for detection of the other species, etc. Correction is requested.

Status of Claims:

2. No claims are allowed.

WO 94/28174 A describes probes for detecting bacteria of the genus *Legionella* by means of a sandwich hybridization method, said probes specifically hybridizing to sequences of the 16s region at a temperature of between 35C and 65C. However, the reference does not teach the use of the specific probes set forth in the instant claims or the use of them for species detection too.

Cockerill III et al (US Patent No. 6,830,888) and Beimfohr et al (WO2002102824-A2) discloses a probe which is 100% identical to the probe recited as Applicant's SEQ ID NO: 2, neither reference recites any of the other sequences, e.g., SEQ ID Nos: 1 or 3-8. Accordingly, the references do not teach or suggest the claimed invention.

Grimm et al. (Appl.and Environ.Microbiol. July 1998. 64(7): 2686-2690) teaches a method of determining *L.pneumophila* using a 16S rRNA oligonucleotide sample which hybridizes specifically at 43C. However, the reference does not teach use of the specific probes recited in the instant claims.

Roth (WO 02/70728) and Hogan (US 6,326,486) teach longer nucleotide sequences with similarity to the claimed sequence, but do not teach the exact probes. Further, these references are drawn to *Enterobacteriae*, not *Legionella*.

Correspondence regarding this application should be directed to Group Art Unit 1645. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Remsen. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November

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15,1989). The Group 1645 Fax number is 571-273-8300 which is able to receive transmissions 24 hours/day, 7 days/week.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer E. Graser whose telephone number is (571) 272-0858. The examiner can normally be reached on Monday-Thursday from 8:00 AM-6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi, can be reached on (571) 272-0956.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-0500.

/Jennifer E. Graser/
Primary Examiner, Art Unit 1645

12/16/08